

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE Examiner Lyle A. Alexander

ART UNIT 1743

In re application of E. Alan Bates et al. Application No. 08/935,629 Filed 09/23/97 For ASSAYING DEVICE ....

### CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper or fee referred to as being attached or enclosed) is being deposited with the U.S. Postal Service in an envelope with sufficient postage as first class mail addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on

Typed Name: Daniel A. Sullivan, Jr.

Date of Signature:  $\frac{9/23/99}{}$ 

TRANSMITTAL OF APPELLANT'S BRIEF

**Assistant Commissioner for Patents** Washington, DC 20231

Enclosed herewith is APPELLANT'S BRIEF in triplicate, together with a check in the amount of \$150 to cover the requisite fee.

Respectfully submitted,

Daniel A. Sullivan Jr. Attorney for the Applicant

Reg. No. 25068

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner Lyle A. Alexander ART UNIT 1743

#11.5 er 106.99

In re application of E. Alan Bates et al. Application No. 08/935,629 Filed 09/23/97 For ASSAYING DEVICE ....

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9/24/99

Signed: Daniel

Typed Name: Daniel A. Sullivan, Jr.

Date of Signature: \_

9/23/99

APPELLANT'S BRIEF

Assistant Commissioner for Patents Washington, DC 20231

#### (1) REAL PARTY IN INTEREST

The real party in interest is DTx, Inc., a Delaware corporation.

## (2) RELATED APPEALS AND INTERFERENCES

There are no pending appeals or interferences known to appellant or the appellant's legal representative, which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

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#### (3) STATUS OF CLAIMS

All of the claims in this application, i.e. claims 1, 8 and 23-41, are pending, rejected and appealed.

#### (4) STATUS OF AMENDMENTS

Two amendments were filed subsequent to final rejection, one, entitled AMENDMENT UNDER 37 CFR 1.116, on 06/14/99 and the other, entitled SUPPLEMENTAL AMENDMENT UNDER 37 CFR 1.116, on 07/12/99. That of 06/14/99 was refused entry, and that of 07/12/99 was to be entered upon the filing of this BRIEF.

#### (5) SUMMARY OF INVENTION

All Fig. and page references in this section are to the Figs. and specification pages of this application. A copy of the specification with line numbers is attached as Appendix II for the convenience of the Board. Locations of text inserted by amendment are indicated by the circled numbers 1-5 on page 3 and the corresponding insertions are presented on the page at the end of Appendix II. Two amendments of numerals are indicated in lines 10 and 11 of page 4. A copy of the drawings as amended is attached as Appendix III.

With reference first to Fig. 1, and as explained at page 3, lines 16-19, an assaying or drug screening device of the invention includes a cartridge/cassette 1 having a broad, lateral face 1a, a narrow, lateral face 1b, and a narrow end face 1c. Window 2 permits viewing test results on a test strip 3. Well/opening 4, situated on the broad lateral face 1a, has a top in the area of its top edge 4a. As drawn in Fig. 1, one can see that the well/opening 4 extends from its top at edge 4a into the cartridge/cassette to surround an empty space 4b for reception of sample.

Fig. 1 in exploded view and Fig. 2 in assembled view illustrate the relationship of cap/cover 5 with cartridge/cassette 1. This relationship is explained at page 3, lines 18-25. After sample has been dropped into well/opening 4 using a pipette for instance, cap/cover 5 is put in place, as shown in Fig. 2, to seal the top of the well/opening. Space 4b becomes a chamber for retention of sample. The cap/cover 5 passes around or encircles the cartridge/cassette at 5a (Fig. 2), to constrain the cap/cover in a fluid tight relationship against the top of the well/opening.

Fig. 3, as explained at page 4, lines 1-4, shows an embodiment in which the cartridge/cassette 1 has two windows 2, two test strips 3, and two well/openings connected by a channel.

In Fig. 4 (page 4, lines 5-8), raised edge 6 and indentations 7 cooperate to insure attachment of the cartridge/cassette 1. Similar action is provided by indentation 8 and button 9 of Fig. 5 (page 4, lines 9-14).

After the cap/cover 5 has been attached, the cartridge/cassette may be placed on a photocopier for photocopying of the test results showing in window 2.

#### (6) ISSUES

The issues presented for review are:

Issue 1. Are claims 25-26 rejectable under 35 USC 112, second paragraph, as being indefinite?

Issue 2. Are claims 1, 8, and 23-41 rejectable under 35 USC 102(b) on Senior (USP 5,504,013)?

#### (7) GROUPING OF CLAIMS

For the ground of rejection corresponding to Issue 2, claims 1, 8, and 23-41 do not stand or fall together.

#### (8) ARGUMENT

#### Issue 1

The rejection as detailed in the final action mailed 04/28/99 states that claim 25 is confusing as to what is intended by the "space being empty".

The referenced space is defined in parent claim 24. In terms of the drawings, well/opening 4 in Fig. 1 is drawn so that one can look down into it, and, on this basis, applicant has specified in claim 25 that the space of claim 24 is an empty space.

The specification that the space is empty has special relevance in terms of a distinction over Senior, because, in Senior, bibulous member 16 fills the sample-receiving opening in Senior's housing and even protrudes out of it.

For these reasons, the specification of claim 25 that the space is empty is not confusing, and reversal of the rejection under Issue 1 is requested.

#### Issue 2 - Introduction

A basic principle of rejections under 35 USC 102(b) is that the reference must show every feature mentioned in the claims. The Manual of Patent Examining Procedure, Section 2131, entitled "Anticipation - Application of 35 USC 102(a), (b), and (e)", quotes as follows: Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) - "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described,

in a single prior art reference.", <u>Richardson v. Suzuki Motor Co.</u>, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) - "The identical invention must be shown in as complete detail as is contained in the ... claim.".

Before showing how the individual claims avoid anticipation rejections on Senior, it will be helpful to point out, in general, that the present invention and Senior differ fundamentally in approach. Thus, as brought out, for instance, on page 3 of the present specification, lines 18 and 19, sample measured in drops is of concern, and the structural characteristics and methodology set forth in the claims are chosen correspondingly. The intentions of Senior are entirely different. In Senior, urine is not added dropwise, but, instead, an inundation of a bibulous member 16 occurs using a stream of urine. With member 16 then soaked, it is proposed in Senior to remove cap 15 from a window 17, bring the cap around, and slide the cap over member 16 into place on portion 13. Needless to say, and despite the wishes of Senior, this provides numerous opportunities for urine to drip or be squeezed from member 16 onto hands, clothes, furniture and floor. Furthermore, there is opportunity to come into contact with the soaked member 16. Another difficulty is that member 16 can be hit and bent during the process of attempting to slide the cap over it.

There follows, now, a detailing of the manner in which the separate claims under Issue 2 avoid anticipation by Senior. For dependent claims, often only their relevant additional features are specified, it being understood that previously specified features of the parent claim or claims apply as well. In the case of some dependent claims, however, cooperation of their features with those of parent claims are especially pointed out.

Claim 1 specifies that the cap/cover seals the top of the well/opening in a fluid tight relationship. In Senior, the opening is in the end of portion 13. Member 16 protrudes out of the opening. When cap 15 is in place, sample can still move out of the top of the opening, into the protruding member 16. In Senior, to the extent that there may be a sealing action performed by Senior's cap 15, it appears to be along the sides of extended portion 13, rather than at the top of the opening. However, there is no exact specification in Senior of where a sealing action is located between the cap 15 and the extended portion 13 or casing 10.

Paragraph a. in col. 5 of Senior has been noted, but this does not inherently lead to a structure where the cap seals the top of the aperture. For instance, said paragraph a. could be accomplished by cutting member 16 off flush with the end of portion 13. This would not change the fact that sample could still move out of Senior's opening, into the interior of cap 15 and that any sealing appears to be along the sides of extended portion 13.

The situation in Senior is to be contrasted with the situation in the present invention which has the top of the well/opening sealed in a fluid tight relationship.

#### Issue 2 - Claim 8

Independent claim 8 adds over claim 1 the specification of a drug screening device in the preamble and a drug test strip in the body of the claim. Senior does not disclose either a drug screening device or a drug test strip, and instead mentions pregnancy testing, so that claim 8 avoids the anticipation rejection for these reasons in addition to the reasons discussed above for claim 1.

This claim is for a method of using the assaying device of claim 1 and includes steps of depositing the sample into the well/opening (the example disclosed is dropping sample from a pipette) and attaching the cap/cover means to seal the top of the well/opening in a fluid tight relationship. Senior, in contrast, runs a stream of urine against a bibulous member 16 and does not seal the top of the opening in the end of extended portion 13.

#### Issue 2 - Claim 24

This claim provides that there is a sample-receiving space extending into the cartridge/cassette means from the sealable top of the well/opening. While Senior's col. 1, line 52, col. 4, line 16, and col. 5, line 30, may indicate that the bibulous member has some extent from the opening of extension 13 into its interior, Senior does not disclose the association of a sealable top and a sample-receiving space extending inwards therefrom, as required by this claim 24.

#### Issue 2 - Claim 25

Claim 25 specifies that the space defined in claim 24 is empty. In contrast, bibulous member 16 fills the opening in the end of extended portion 13 in Senior. Paragraph a. in col. 5 of Senior does not inherently disclose a structure meeting the feature of claim 25, because paragraph a. could be accomplished by cutting member 16 off flush with the end of portion 13. Directing a urine stream (Senior, e.g., col. 4, line 45) into an empty space of this claim 25 would result in turbulence, overflow, and splashing. The apparatus of Senior and that of the present invention have differing structural features, to support the different ways in which they are to be used.

In contrast to the sealed chamber of this claim extending from the top of the well/opening into the cartridge/cassette, Senior can have urine in its cap outside of the top of its opening.

#### Issue 2 - Claim 27

This claim relates to placing the well/opening such that it can face upwards in a most stable orientation of the cartridge/cassette. The cartridge/cassette is then especially resistant against tipping when and after the pipette is brought into position for deposit of sample. Senior does not disclose its opening on a broad lateral face of its extension 13, but rather on the end of the extension. Urine can drip or spill from the bibulous member onto objects below, such as a table or floor, and onto the interior surface of the cap, once the cap is in place. The location on extension 13 of the one or more apertures mentioned in paragraph a. of col. 5 of Senior is not disclosed by Senior, other than the aperture shown in Senior's drawings in the end of 13.

#### Issue 2 - Claims 28 and 29

These claims are directed to the features that the cap/cover means passes around or completely encircles the cartridge/cassette, in order to hold a fluid tight seal. The exact location of the possible seal discussed in Senior beginning at col. 2, line 33 is not disclosed. Neither does Senior show the combined interaction between the top of the sample well/opening and the cap/cover means resulting from the dependence of claims 28 and 29 on claim 27.

#### Issue 2 - Claims 30-32

Claims 30-32 correspond to claims 24-26 and combine the specially oriented well/opening of claim 27 with the features of a sample-receiving space inwards of the sealable top, the empty space, and the sample-retaining chamber. While Senior's opening is not so specially oriented, neither does

it disclose the cooperation between the sealable top and the inwards lying sample space, nor does it disclose an empty space or a sample-retaining chamber inwards of the sealed top.

#### Issue 2 - Claims 33 and 34

These claims correspond to claims 28 and 29 but depend from claim 32, in order to group together the features of the specially oriented well/opening of claim 27, the empty space, and the sample-retaining chamber with the features that the cap/cover means passes around or completely encircles the cartridge/cassette, in order to hold a fluid tight seal. The exact location of the possible seal discussed in Senior beginning at col. 2, line 33 is not disclosed, but, with Senior's opening being on the end of 13, Senior certainly does not disclose the sealing of the top of a well/opening on the broad lateral face of its extension 13.

#### Issue 2 - Claims 35 and 36

Senior does not disclose, either expressly or inherently, the doubling of structures specified in claim 35, nor does it disclose a channel connecting two well/openings, as shown on the right end of the cartridge/cassette in Fig. 3, and as claimed in claim 36.

#### Issue 2 - Claims 37 and 38

Senior has no disclosure of the interlocking indentions, raised edge and buttons of these claims.

#### Issue 2 - Claims 39 and 40

Senior does not drop sample (claim 39), more specifically from a pipette (claim 40), into an empty well/opening, but rather runs a stream of urine against a bibulous member, which fills, and extends from, an opening in the end of its extension 13, nor does Senior then seal the top of the specially oriented, or located, well/opening of claim 27, as specified by these method claims.

In contrast to the specifications of claim 41, Senior does not place a cartridge/cassette on a photocopier, to photocopy test results showing in a window. Senior mentions a reader/microprocessor, not a photocopier. Details of how Senior's reader/microprocessor works are not disclosed.

#### Conclusion

For the reasons given, the rejections associated with Issues 1 and 2 are not well founded.

Reversal of the rejections of all of claims 1, 8 and 23-41 is in order and is requested.

Respectfully submitted,

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#### (9) APPENDIX I

A copy of the claims involved in the appeal follows:

- 1. An assaying device for depositing and analyzing a sample, comprising:
- a a cartridge/cassette means which contains a test strip, a window for viewing test results and a well/opening separate from the window, having a top and serving for deposit of the sample, and
- b. a cap/cover means for sealing the top of the sample well/opening in a fluid tight relationship following deposit of the sample.
  - 8. A drug screening device for depositing and analyzing a urine sample, comprising:
- a a cartridge/cassette means which contains a drug test strip, a window for viewing test results and a well/opening separate from the window, having a top and serving for deposit of the urine sample, and
- b. a cap/cover means for sealing the top of the sample well/opening in a fluid tight relationship following deposit of the sample.
- A method of using an assaying device as claimed in claim 1, comprising the steps of:
  depositing the sample into the well/opening, and attaching the cap/cover means to cover and seal the
  top of the well/opening in a fluid tight relationship.
- 24. An assaying device as claimed in claim 1, the well/opening extending from its top into the cartridge/cassette means to surround a space for reception of sample.
  - 25. An assaying device as claimed in claim 24, the space being empty.
- 26. An assaying device as claimed in claim 25, the cap/cover means when sealing the top of the sample well/opening transforming said space into a chamber for retention of sample.

- 27. An assaying device as claimed in claim 1, the well/opening being situated on a broad, lateral face of the cartridge/cassette means.
- 28. An assaying device as claimed in claim 27, the cap/cover means when sealing the top of the sample well/opening passing around the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.
- An assaying device as claimed in claim 28, the cap/cover means when sealing the top of the sample well/opening completely encircling the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.
- 30. An assaying device as claimed in claim 27, the well/opening extending from its top into the cartridge/cassette means to surround a space for reception of sample.
  - 31. An assaying device as claimed in claim 30, the space being empty.
- 32. An assaying device as claimed in claim 31, the cap/cover means when sealing the top of the sample well/opening transforming said space into a chamber for retention of sample.
- 33. An assaying device as claimed in claim 32, the cap/cover means when sealing the top of the sample well/opening passing around the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.
- 34. An assaying device as claimed in claim 33, the cap/cover means when sealing the top of the sample well/opening completely encircling the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.
- 35. An assaying device as claimed in claim 1, the cartridge/cassette means containing a second test strip, a second window for viewing test results and a second well/opening having a top

and serving for deposit of the sample, whereby there are two well/openings whose tops are sealed by the cap/cover means in a fluid tight relationship following deposit of the sample.

- 36. An assaying device as claimed in claim 35, said two well/openings being connected by a channel.
- 37. An assaying device as claimed in claim 1, the cartridge/cassette means having a raised edge and the cap/cover means having indentations, the raised edge and the indentations, when snapped together, insuring the attachment of the cartridge/cassette means with the cap/cover means.
- 38. An assaying device as claimed in claim 1, the cartridge/cassette means having an indentation and the cap/cover means having a raised button, the indentation and button, when snapped together, insuring the attachment of the cartridge/cassette means with the cap/cover means.
- A method of using an assaying device as claimed in claim 31, comprising the steps of: dropping the sample in the form of urine into the well/opening, and attaching the cap/cover means to cover and seal the top of the well/opening in a fluid tight relationship.
  - 40. A method as claimed in claim 39, wherein the dropping is done from a pipette.
- 41. A method as claimed in claim 23, further comprising, following the step of attaching, the additional steps of placing the cartridge/cassette on a photocopier and photocopying test results showing in the window.

Dix 1 of /

# APPENDIX I - 08/935,629

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AN ASSAYING DEVICE CONSISTING OF THE TEST CARTRIDGE OR

CASSETTE WITH A CAP OR COVER WHICH ATTACHES ONTO THE

CARTRIDGE OR CASSETTE TO COVER AND SEAL THE WELL OR OPENING

INTO WHICH THE SAMPLE HAS BEEN DEPOSITED

## BACKGROUND

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This invention generally relates to assaying devices and in particular the on-site immunoassay technology used to detect the presence of drugs in urine. On-site drug tests generally use an immunoassay method called antigen-antibody competitive binding to screen for the presence of drugs. Among the test kits used for such testing there are tests composed of a housing or container which contains a reagent test strip, an opening in which test results are displayed and a place for deposit of the sample. The sample wicks up into the reagent test strip and the results are displayed. The results are generally available within a few minutes. Often it is desirable to make a photocopy of the results, whether positive or negative, for a permanent record, since test results will change or disappear over time.

Possible problems include spilling of the sample, contamination of the sample, and contact by the test administrator or others with the sample during handling. A method is needed for a cleaner, more sanitary and easier handling of the test housing during and after the test administration, especially since specimens can be infectious. In order to photocopy the results, the test device is placed face down on the copier, so it is desirable to insure that sample will not leak onto the copier. Also a method is needed to insure a second sample from another donor is not inadvertently placed in the same test cartridge/cassette.

#### SUMMARY OF THE INVENTION

The housing or cartridge/cassette of the present invention will have one or two openings or "windows" in which the test results are displayed and one or two wells or openings in the top of the cartridge/cassette for deposit of the sample. The sample is placed in the

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well/opening by use of a pipette. The results will be displayed in the window. The cartridge/cassette and the cap or cover of the present invention will prevent the sample used in the test from spilling out, will prevent contamination of the sample, and will permit cleaner, more sanitary and easier handling of the cartridge/cassette during and after the wicking test process. The cap/cover when placed on the cartridge/cassette will provide a fluid tight relationship. The cartridge/cassette with the cap/cover provide a compact, easy to handle unit. The cap/cover if placed on the cartridge/cassette as soon as the sample begins wicking will prevent inadvertent commingling or intermixing of another sample.

It is the principal object of this invention to provide a convenient, compact, easily managed device for the containment of the sample.

It is also a further objective to provide a means to protect the sample from contamination once placed into the test well/opening.

It is a further objective to provide a means to protect the test administrator from undesirable contact with the sample while handling the test cartridge during the test administration.

It is a further objective to provide a means to protect the test administrator or others from undesirable contact with the sample during subsequent handling of the test cartridge.

It is a further objective of the present invention to provide a means of insuring that while photocopying the test results displayed in the test cartridge/cassette the sample will not leak from the well/opening onto the copier.

It is a further objective of the present invention to provide a means to prevent the test administrator from inadvertently commingling or intermixing a second sample from another donor.

These and other objects of the present invention will become readily apparent upon further review of the following specifications and drawings.

## BRIEF DESCRIPTION OF THE DRAWING

In the Drawing:

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Figure 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top;

Figure 2 is a perspective view of the cartridge/cassette and cap/cover snapped or slipped together as seen from the front;

Figure 3 is a perspective view of the cartridge/cassette with two windows and two sample well/openings and the cap/cover separately as seen from the front or top.

Figure 4 is a side view of the cartridge/cassette and of the cap/cover (shown in cross section) showing the addition of edges on the cartridge/cassette and indentations on the cap/cover for further securing the cap/cover.

Figure 5 is a side view of the cartridge/cassette and of the cap/cover (shown in cross section) showing the addition of indentations on the cartridge/cassette and raised buttons on the cap/cover for further securing the cap/cover.

## J DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top. The cartridge/cassette 1 contains an opening or window 2 in which the results on the test strip 3 will be displayed. The sample will be dropped into the well/opening 4 by means of a pipette. The cap/cover 5 has not been placed onto the cartridge/cassette yet.

Fig. 2 is a perspective view showing the cartridge/cassette and cap/cover snapped or slipped together. Fig. 2 is a view as seen from the front or top. The cartridge/cassette 1 with the results window 2 has the cap/cover 5 snapped or slipped into place. The sample well/opening, 4 in the other Figures, is now covered and sealed by the cap/cover 5 in a fluid tight relationship.

Fig. 3 shows a cartridge/cassette 1 with two results windows 2, two test strips 3, two sample well/openings with a connecting channel 4 and a separate cap/cover 5. This type of cartridge/cassette will accommodate more separate tests and requires a greater quantity of the sample.

Fig. 4 shows a side view of the invention with the side of the cap/cover 5 cut away. The cartridge/cassette 1 is designed with a raised edge 6 and the cap/cover (shown in cross section) with indentations 7 which when snapped together will further insure the attachment.

Fig. 5 shows a side view of the invention with the side of the cap/cover 5 cut away. The cartridge/cassette 1 is designed with an indentation and the cap/cover (shown in cross section) with a raised button which when snapped together will further insure the attachment. The end of the cartridge/cassette where the well/opening is located has been reduced in thickness with the result that when the cap/cover is attached it will be flush with the edges of the cassette/cover.

Although the embodiments described herein are the preferred one, modifications can be made to the shape of the cartridge/cassette and the cap/cover, without departing from the spirit and scope of this invention. The cartridge/cassette and the cap/cover may be formed or molded from any suitable material, usually plastic or other similar material, but the invention should work as well with most drug test materials. The cap is effective if it slips onto the cartridge/cassette snugly enough to insure that it will cover and seal the top of the sample well in a fluid tight relationship and will not detach. Raised buttons or edges can also be incorporated into the design of the cartridge/cassette and cap/cover to further insure that the cap/cover when snapped or slipped into place will not detach from the

available, but more will not depart from the spirit and scope of this invention.



## **ABSTRACT**

An assaying device composed of a test cartridge/cassette and cap/cover. When attached, the cap/cover set top of a sample well/opening on the cartridge/cassette in a fluid tight manner, to protest from contact with and contamination of the tested sample (for example, urine for drug testing), provide easier, cleaner handling of the test cartridge/cassette and prevent intermixing of another sample.

Page 3, line 18, between "will be displayed." and "The sample" insert the sentence --As viewed in Fig. 1, cartridge/cassette 1 shows a broad, lateral face 1a, a narrow, lateral face 1b, and a narrow end face 1c.--

Page 3, line 19, between "well/opening 4" and "by means" insert --on lateral face 1a--.

Page 3, line 19, between "of a pipette." and "The cap/cover" cancel the sentence presented in the AMENDMENT of 11/16/98 and substitute therefor the following revised sentence: --Well/opening 4, which is separate from window 2, has a top in the area of top edge 4a and extends from there into the cartridge/cassette to surround empty space 4b for reception of the sample.--.

Page 3, line 22, after "slipped together" and before the first period, insert --following deposit of the sample--.

Page 3, line 25, after "fluid tight relationship." add --By sealing the top of the sample well/opening, the cap/cover 5 transforms space 4b into a chamber for retention of sample while the sample wicks for the test. As indicated by the cap/cover region 5a showing in Fig. 2, when assembled with the cartridge/cassette, the cap/cover passes around, and, in fact, encircles, the cartridge/cassette, in order to hold the cap/cover in a fluid tight relationship against the top of the sample well/opening.--

APPENDIX III - 08/935,629

Lawright 116/98

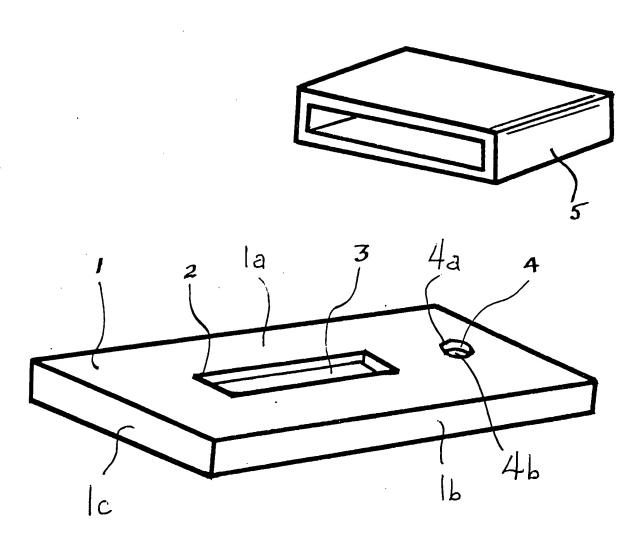


FIG. I

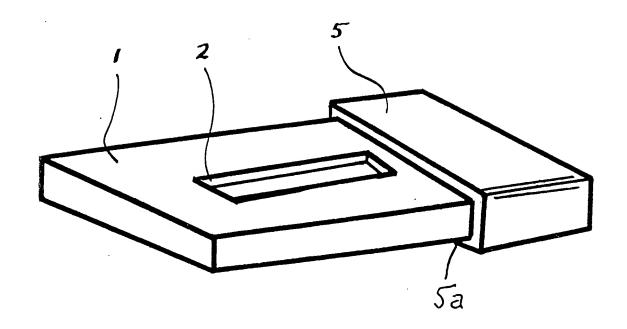


FIG.2

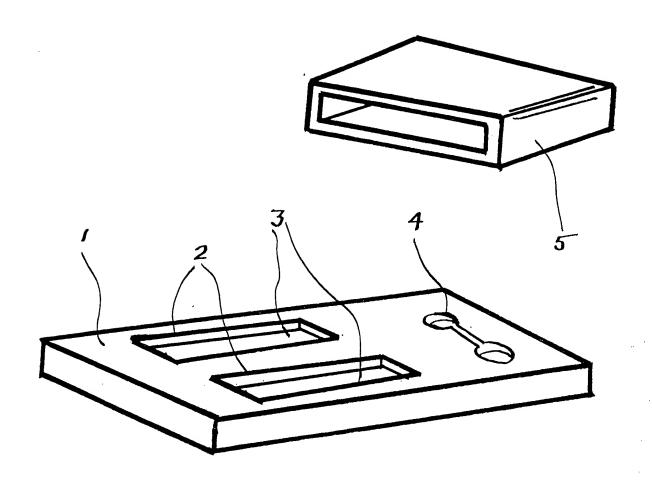
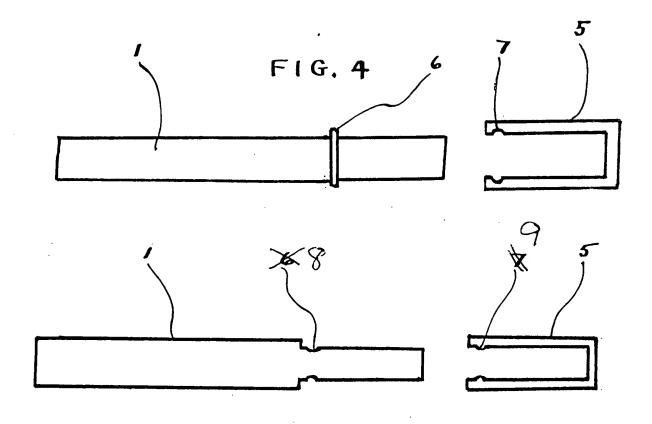


FIG.3



F1G. 5